

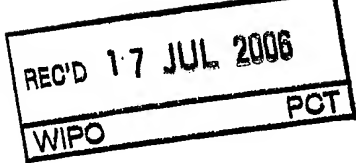
## PATENT COOPERATION TREATY


## PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)



Applicant's or agent's file reference 6395-68278-02		<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/US2005/011086		International filing date (day/month/year) 01.04.2005		Priority date (day/month/year) 02.04.2004
International Patent Classification (IPC) or national classification and IPC INV. A61M11/00 B05B17/06				
Applicant THE GOVERNMENT OF THE UNITED STATES OF... et al.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 9 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 8 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input checked="" type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  08.06.2006		Date of completion of this report  14.07.2006		
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer  Borowski, A  Telephone No. +49 89 2399-2758		



**INTERNATIONAL PRELIMINARY REPORT  
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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
  - ☐ international search (under Rules 12.3(a) and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4(a))
  - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-28 as originally filed

**Claims, Numbers**

1-63 received on 09.06.2006 with letter of 07.06.2006

**Drawings, Sheets**

1/17-17/17 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,  
☒ claims Nos. 26-58

because:

- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).
- ☒ no international search report has been established for the said claims Nos. 26-58
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13ter.1(a) or (b) and 13ter.2.
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
- ☒ See separate sheet for further details

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**Box No. IV Lack of unity of invention**

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1. ☐ In response to the invitation to restrict or pay additional fees, the applicant has, within the applicable time limit:
- ☐ restricted the claims.
  - ☐ paid additional fees.
  - ☐ paid additional fees under protest and, where applicable, the protest fee.
  - ☐ paid additional fees under protest but the applicable protest fee was not paid.
  - ☐ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
  - ☒ the parts relating to claims Nos. 1-25,59-63 .

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1-25,59-63
	No: Claims	
Inventive step (IS)	Yes: Claims	1-25,59-63
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-25,59-63
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VII Certain defects in the international application**

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The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

Claim 58 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT: *a method of using an aerosolizing device for administering an aerosolized agent to a patient*. For said claim no international search report had been established and, consequently, no examination has been carried out with respect to the novelty, inventive step and industrial applicability of the subject-matter of this claim (Article 34(4)(a)(I) PCT).

The applicant had not paid the additional search fees for claims 26-57, therefore no international search report has been established for said claims. Consequently, the present written opinion does not cover said claims 26-57 (PCT Guidelines 17.60).

**Re Item IV**

**Lack of unity of invention**

This International Preliminary Examination Authority considers that there are the following 3 (groups of) inventions claimed in the international application:

- i) claims 1-25 and 59-63, which essentially define an aerosolizing element comprising a movable element being capable of moving in response to an external force;
- ii) claims 26-41, which essentially define an aerosolizing device including a disposable aerosolizing element being removable from the housing of the aerosolizing device;
- iii) claims 42-57, which essentially define an aerosolizing device including a disposable aerosolizing element, wherein the element prevents the agent to be expelled, from contacting an actuator.

These 3 inventions are not so linked that they form a single general inventive concept (Rule 13.2 PCT). The single general inventive concept linking the inventions according to different claims can be defined by the common features of these claims. In the present case these common features are:

- between claim 1 and any of claims 26 or 42: a removable aerosolizing element capable of expelling an aerosolized agent ;

- between claims 26 and 42: an aerosolizing device comprising a housing, a disposable aerosolizing element capable of expelling aerosolized agent, an oscillator/actuator positioned to exert vibratory oscillations on a portion of the disposable aerosolizing element to aerosolize agent in the element, and a patient interface shaped to deliver aerosolized agent expelled from the disposable aerosolizing element to a patient.

An aerosolizing element and an aerosolizing device according to these features, however, are known from the document US2003/0164169 (see figures 4A-4C for example).

The features of each group which are not common with any of the other groups address different objective technical problems. Said problems may be regarded as being:

- i) how to provide dose of an agent for aerosolization, which can be stored and aerosolized in a convenient way;
- ii) how to provide a compact aerosolizing device;
- iii) how to prevent contamination of the aerosolizing device.

Consequently, the single general concept in the present case is not novel (and hence non inventive) and the application, therefore, does not comply with the requirements of unity of invention (Rule 13.1 PCT).

#### **Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

Reference is made to the following documents:

D1: EP-A-1 149 602 (MICROFLOW ENGINEERING SA) 31 October 2001 (2001-10-31)

1. Document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows a removable (column 10, lines 49-52) aerosolizing element (5) suitable for use in an aerosol delivery device (1), comprising:  
a body (8, 18) having an exterior surface and a chamber (9) defined therein;  
an inlet (7) defined in the body for connection to a source of agent, the inlet being in fluid communication with the chamber;

agent releasing orifices (14, 15) defined in the body and in communication with the chamber;  
a moveable element (8, 8a) having an inner surface that defines a portion of the chamber, the moveable element being capable of moving in response to an external force applied to the outer surface to expel agent in the chamber through the orifices (column 7, lines 34-39); and  
projections disposed in the chamber and being configured to contact the inner surface of the inner surface opposing to the moveable element (the portions of the substrate (18) surrounding the cavities (13) are considered as projections).

The subject-matter of claim 1 differs from this known aerosolizing element in that the projections are configured to contact both: the inner surface of the moveable element and the opposing inner surface when the external force is applied to the exterior surface.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

The problem to be solved by the present invention may be regarded as how to maintain a minimum spacing between the moveable element and the orifices, to maintain adequate capillary head without undue pressure loss.

The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT). Such solution is neither disclosed nor suggested by any of the available prior art documents. Especially D1 is silent as to whether the portions of the top substrate (18) surrounding the cavities (13) are capable of contacting the bottom substrate in use to maintain a minimum spacing in the chamber.

2. Claims 2-24 and 59-63 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

### **Re Item VII**

#### **Certain defects in the international application**



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1. The independent claim 1 has not been drafted in the two-part form, as normally required by Rule 6.3(b) PCT.
2. The features of the claims have not been provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. Claims 24, 25 and 59-63 have not been numbered as required by Rule 6.4(c) PCT.

**Re Item VIII**

**Certain observations on the international application**

Claim 61 defines a product in terms of the process by which the product is made. The claim should have been constructed as a claim to the product per se that possesses the characteristics derived from the manufacturing process stated in the claim.